

Title: Parent eReferral to Tobacco Quitline in Primary Care

Short Title Parent eReferral to Tobacco Quitline

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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse event
SHS	Secondhand Smoke
EHR	Electronic Health Record
CDS	Clinical Decision Support
NRT	Nicotine Replacement Therapy
DBHi	Department of Biomedical and Health Informatics

ABSTRACT

Context: (Background)

Secondhand smoke (SHS) exposure is a significant public health problem in that it both harms children and is widely prevalent, affecting more than 40% of US children. Tobacco cessation quitlines are effective in helping smokers quit, but few smokers make use of their services. Electronic health record-based systems that automate referral of interested parents to quitlines through pediatric settings may increase the proportion of smokers who successfully enroll in treatment.

Objectives: (primary and important secondary objectives)

Primary Objective: To compare through a randomized clinical trial parent smoker enrollment in the tobacco quitline using an electronic referral process (parent information sent to quitline with quitline calling the parent) to the current standard manual process (giving the parent the quitline phone number).

Secondary Objective: To explore certain parent and child factors associated with successful enrollment in and willingness to receive services from the tobacco quitline in order to inform future interventions that maximize impact.

Study Design:

We propose a randomized controlled study of electronic quitline referral compared to standard practice. Parent enrollment in the quitline will be reported to the study team by the state tobacco quitline, managed by the Pennsylvania Department of Health.

Setting/Participants:

This is a single site study at one large outpatient pediatric practice (Karabots). Eligible study participants are parents/caregivers (hereafter referred to as “parents”), 18 years of age or older, who are present for the child’s healthcare (both well-child and acute) visit, who smoke, and who are interested in receiving treatment through the tobacco quitline.

Study Interventions and Measures:

The intervention is electronic referral to the tobacco quitline for parent smokers. The referral process will be embedded in a tobacco treatment clinical decision support (CDS) tool, created to help pediatricians provide counseling and treatment to parent smokers. The primary outcome of interest is smoker enrollment in the quitline, defined as the proportion of parent smokers identified in the clinic that enroll in quitline treatment compared across the intervention (electronic referral) and control (standard practice) approaches. Secondary outcomes include patient and parent demographic and behavioral factors associated with successful enrollment.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Secondhand smoke (SHS) exposure is a significant public health problem in that it both harms children, increasing their risk of acute respiratory infections, asthma exacerbations, sudden infant death syndrome, and premature death,(1) and is widely prevalent, affecting more than 40% of US children.(2) When a parent quits smoking, they eliminate the majority of their children's SHS exposure,(1)(3)(4) decrease the risk of their children becoming smokers when they grow up,(5) and increase their own life expectancy by an average of 10 years.(6) Pediatricians are uniquely positioned to educate and motivate parents towards protecting their children from SHS.(7) Parents who smoke are often underserved medically, but see their child's doctor an average of 4 times each year, significantly more than they themselves see a clinician.(8) Parents expect their pediatrician to ask about their smoking status and are interested in their pediatrician providing smoking cessation medication and connecting them to additional resources,(9) such as tobacco counseling quitlines.(10) Despite this opportunity to intervene, pediatricians rarely provide such treatments.(11) Nationally, of parents who smoke who had accompanied their child to the pediatric clinician in the past year, only 38% were advised to quit and 15% had treatment options recommended to them.(9)

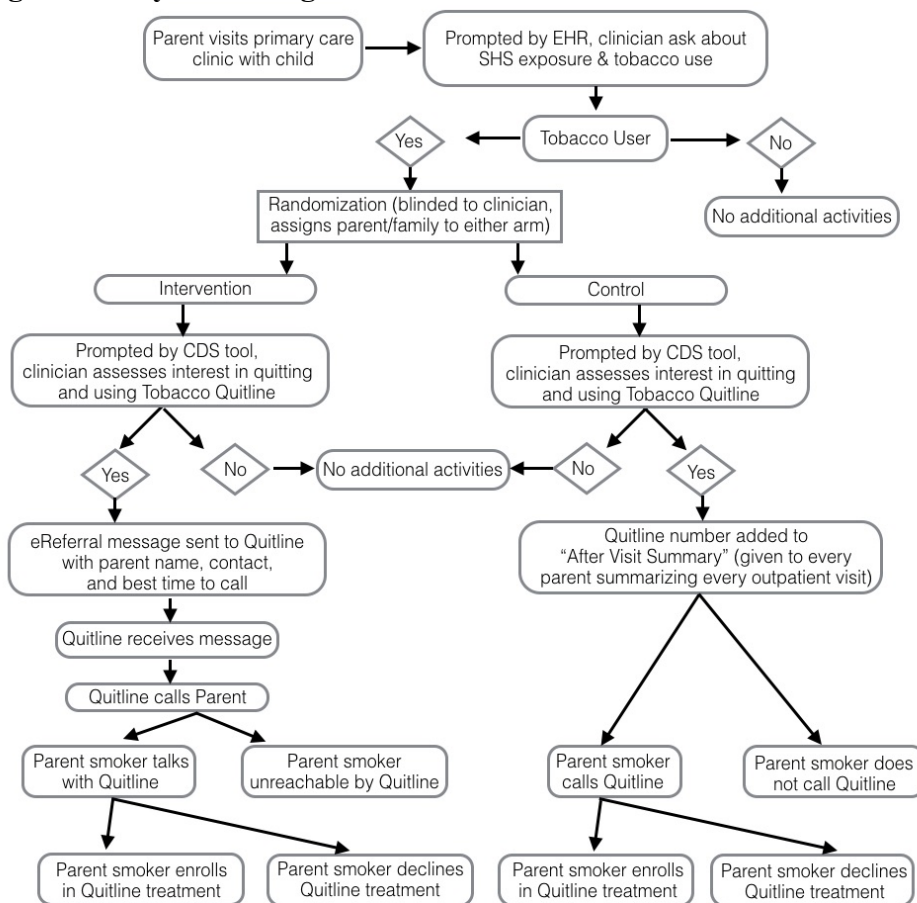
Tobacco cessation quitlines are effective in helping smokers quit,(12)(13) but few smokers make use of their services. Less than 3% of smokers who saw their healthcare provider in the last year report being connected to them, (14) and only 8% of smokers who are trying to quit, and who are aware of quitlines, actually use them. (15) Quitlines provide free (to the user) population-based treatment to tobacco users available through a nationwide consortium (1-800-QUIT-NOW). Telephone counseling can be proactive or reactive. In a proactive approach the counselor initiates one or more calls to provide support in making a quit attempt or avoiding relapse. Reactive counseling in contrast is available on demand for people who smoke, or their friends and family.(13)(16)

Electronic health records (EHRs) and clinical decision support (CDS) systems may improve the quality and standardization of clinical interventions for tobacco use.(17)(18)(19) Additionally, the EHR may reduce the costs and burden of delivering tobacco dependence interventions by efficiently referring smokers to state tobacco quitlines.(19) In adult settings, CDS systems that automate referral of interested patients to quitlines significantly increase the proportion of smokers who successfully enroll in treatment.(20)(21) Use of CDS tools help pediatric clinicians provide counseling and prescribe nicotine replacement therapy (NRT) to parents who smoke in pediatric primary care and hospital settings.(22)(23) For pediatric developmental evaluation, automated referrals to early intervention (EI), compared to the standard practice of handing the parent a phone number and asking him or her to make the connection, are strongly associated with completion of multidisciplinary evaluation by EI.(24) No pediatric-based studies have evaluated automated electronic referral to quitlines with proactive counseling compared to standard practice (giving the parent the quitline phone number) for parent smoker enrollment in the quitline program. We hypothesize that automated electronic referral will increase enrollment into the quitline program compared to standard practices of providing the number quitline number to the parent.

1.2 Name and Description of Investigational Product or Intervention

The electronic quitline referral will be embedded within the Tobacco Treatment CDS tool, CDS system previously developed to help pediatricians provide smoking cessation counseling and treatment to parents who smoke,(22) modeled off the CEASE intervention, an evidence-based approach for implementing smoking cessation treatment of parents in the pediatric setting.(25) The parental tobacco treatment CDS tool, which interfaces seamlessly within the EHR (EpicCare®, Epic Systems, Inc, Verona, WI, USA), prompts the pediatric clinician to ask the parent about smoking status and assess interest in quitting (at all well-child and acute visits), links to an electronic nicotine replacement therapy prescription for parents interested in quitting, and guides appropriate documentation. Electronic referral to the quitline will be made by clicking an automated link embedded in the tool that will send the parent smokers' names and telephone numbers (entered by the clinician) directly to the Pennsylvania (PA) Free Quitline. This approach matches an existing workflow for CDS for other aspects of pediatric care already successfully in use by the practice.(26)(27)(28)(29) Parent information will be sent using secure, HIPAA-compliant methods to transmit protected health information, coordinated by the Department of Biomedical and Health Informatics (DBHi). (See Figure for Study Flow Diagram.)

Figure: Study Flow Diagram



*Note: Behaviors all along referral pathway will be recorded to assess difference between groups

2 STUDY OBJECTIVES

The purpose of the study is to determine if electronic referral to the state tobacco quitline for parent smokers increases program enrollment compared to standard referral practice.

2.1 Primary Objective (or Aim)

To compare through a randomized clinical trial parent smoker enrollment in the tobacco quitline using an electronic referral process (parent information sent to quitline with quitline calling the parent) to the current standard manual process (giving the parent the quitline phone number).

2.2 Secondary Objectives (or Aim)

To explore certain parent and child factors associated with successful enrollment in and willingness to receive services from the tobacco quitline in order to inform future interventions that maximize impact.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

We propose a randomized controlled study of electronic quitline referral compared to standard practice. Parent smokers will be randomized based on patient medical record number. Parent enrollment in the quitline will be reported to the study team by the state tobacco quitline, managed by the Pennsylvania Department of Health.

3.1.1 Screening Phase

Potential parent subjects will be screened using the protocol inclusion and exclusion criteria. Parent subjects will be recruited at their child's medical visit by their pediatric clinician. If parents are interested in using the tobacco quitline, they will be referred either via the standard method or through the electronic referral process.

3.1.2 Study Treatment Phase (start of the study intervention)

Parent subjects will be referred to the tobacco quitline, either through electronic referral (intervention) or the standard manual process (control).

3.2 Allocation to Treatment Groups and Blinding

Randomization to the intervention and control approaches will be based on an automatically generated randomization sequence, managed by an honest broker as part of the Department of Biomedical and Health Informatics (DBHi). This will allow for blinding of the clinicians to the allocation.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject will be up to 6 days, with 1 day of screening, up to 5 days of interactions with the tobacco quitline. Both the parent and the child are considered subjects. The parent receives the intervention but the child's data will also be collected.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at 1 investigative site in the United States at the Karabots Pediatric Care Center, within the CHOP care network at The Children's Hospital of Philadelphia.

Recruitment will stop when approximately 601 parent subjects are enrolled (referred to the quitline via either approach). It is expected that approximately 601 parent subjects will be enrolled to produce 500 evaluable parent subjects. While the parent receives the intervention, the patient child is also considered as a subject as their data will be collected as well. Each of the 601 parent subjects will have a corresponding child subject. Thus, a total of 1202 subjects (601 parents plus 601 related children) will be enrolled.

3.4 Study Population

3.4.1 Inclusion Criteria

Eligible subjects will include parents, 18 years of age or older, present for the child's healthcare (both well-child and acute) visit, who smoke, and who are interested in being referred to the tobacco quitline.

3.4.2 Exclusion Criteria

Exclusion criteria will include parents who smoke but are not present during the visit, who are less than 18 years of age, or who are not interested in referral to the tobacco quitline. Non-English language speakers will not specifically be excluded. Counseling available through the tobacco quitline is available in English and Spanish and can be provided in at least 15 additional languages through a third party.

Subjects that do not meet all of the enrollment criteria will not be enrolled.

4 STUDY PROCEDURES

4.1 Study Treatment Phase

Potential parent subjects will be screened for smoking in the context of their child's medical visit. If a parent smoker is identified and they are interested in treatment, the pediatric clinician will obtain their permission to refer the parent to the tobacco quitline.

4.2 Tobacco Quitline Phase

The PA Free Quitline will reach out to interested parent subjects and provide telephone based counseling (see Section 7.1 for intervention description). The Quitline will collect information regarding parent smoker subject counseling. This information will be

aggregated in monthly reports and will then be sent back to the DBHi team via a secure, HIPAA compliant data exchange system. DBHi will act as an honest broker and provide this information to the study team in de-identified reports.

4.3 Review of Medical Record Phase

DBHi, who will act as an honest broker, will abstract information from the child patient's electronic medical chart and present that information to the study team as a de-identified data set (see section 5.1.1 for variable description).

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

During this study, an honest broker – DBHi – will be providing all data between CHOP and from the PA Free Quitline, presenting information to the study team in de-identified reports.

5.1.1 Information collected from Medical Record Review

DBHi, who will act as an honest broker, will abstract information from the child patient's electronic medical chart and present that information to the study team as a de-identified data set. This data will be merged by DBHi, the honest broker, with data from the Quitline. The following variables will be abstracted:

- Patient age
- Patient race/ethnicity
- Patient insurance status
- Presence of chronic condition (e.g. Asthma)
- Parent baseline smoking characteristics, including:
 - o Number of cigarettes smoked per day
 - o Stage of change assessed by asking if they were planning to quit in the next 30 days or 6 months

In addition to data abstracted from the patients' medical charts, parent smokers who are interested in treatment will have their name and phone contact information entered by the clinician, to be electronically sent to the tobacco quitline.

5.1.2 Information collected from tobacco quitline - Pennsylvania (PA) Free Quitline

The PA Free Quitline will collect the following information from/about parent smoker subjects:

- Parent baseline smoking characteristics, including:
 - o Number of cigarettes smoked per day
 - o Stage of change assessed by asking if they were planning to quit in the next 30 days or 6 months
- Parent smokers who talk with the quitline
- Parent smokers unreachable by the quitline
- Parent smokers who enroll in treatment
 - o Including number of successful calls once enrolled
- Parent smokers who decline to enroll in treatment

This information will be aggregated in monthly reports and will then be sent back to the DBHi team via a secure, HIPAA compliant data exchange system. DBHi will act as an honest broker and provide this information to the study team in de-identified reports.

5.2 Efficacy Evaluations

The primary outcome of interest is smoker enrollment in the quitline, defined as the proportion of parent smokers identified in the clinic that enroll in quitline treatment

compared across the intervention (electronic referral) and control (standard practice) approaches.

Secondary outcomes include patient and parent demographic and behavioral factors associated with successful enrollment. Multivariable logistic regression models will be used to assess the adjusted association of independent variables with dependent variables. Additionally, the RE-AIM conceptual framework – a systematic way to evaluate the impact of public health interventions (30), used in a variety of healthcare settings and for varied conditions (31) – will help contextualize parent enrollment in the quitline and improve understanding of system implementation. The RE-AIM model includes the 5 criteria of reach, efficacy, adoption, implementation, and maintenance. This study will measure reach, efficacy, adoption, and impact. Reach will be calculated as the number of parent smokers who visited the clinic who subsequently talked with the quitline divided by the total number of parent smokers visiting the clinic. Efficacy will be calculated as the total number of parent smokers who visited the clinic who enrolled in treatment with the quitline divided by the total number of parent smokers who visited the clinic who talked with the quitline. Adoption will be measured as the proportion of clinicians who refer parent smokers to the quitline (that is, the proportion of clinicians who use the tool who received the tool prompt). We hypothesize that the efficacy of the standard practice approach will exceed that of the electronic referral approach because parent smokers who followed up with referrals on their own (using the number provided by the pediatric clinician to call the quitline) would be more motivated to enroll in cessation treatment. Thus, we will multiply reach by efficacy to yield a composite measure of overall impact.(21)

5.3 Safety Evaluation

This study presents no more than minimal risk to study participants, as this is a study aimed to improve parent smoker enrollment in the state tobacco quitline. The quitline offers evidence-based tobacco cessation counseling, and referral to this resource is already part of standard practice. The only identifying information that will be collected for the parent subjects will be participants' name and telephone number. Once data collection is completed, the master list containing only the names of the study participants will be deleted. No other PHI identifiers will be collected at any time, and no other PHI identifiers will be stored for parent subjects.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint of interest is smoker enrollment in the quitline, defined as the proportion of parent smokers identified in the clinic that enroll in quitline treatment compared across the intervention (electronic referral) and control (standard practice) approaches.

6.2 Secondary Endpoints

Secondary endpoints will include the reach, efficacy, adoption, and impact of the intervention and control approaches, as described above.

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics for subjects will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.3.2 Efficacy Analysis

The primary analysis will be based on an intention to treat approach and will include all subjects randomized at their referral visit.

The primary efficacy endpoint will be the difference in the proportion of quitline enrollment between intervention and control approaches.

Secondary endpoints will include the difference in reach, efficacy, adoption, and impact of the intervention and control approaches.

6.3.3 Safety Analysis

As this study presents no more than minimal risk to study participants, a safety analysis will not be performed.

6.4 Sample Size and Power

We estimate that enrolling at least 500 parents subjects, 250 in each arm, would provide greater than 80% power to detect an absolute difference of at least 6% in enrollment between the intervention and control groups, an effect difference identified in comparable adult studies.(21)(20)

7 STUDY INTERVENTION

7.1 Description

Intervention – electronic referral to quitline

The electronic quitline referral will be embedded within the Tobacco Treatment CDS tool, a CDS system previously developed to help pediatricians provide smoking cessation counseling and treatment to parents who smoke,(22) modeled off the CEASE intervention, an evidence-based approach for implementing smoking cessation treatment of parents in the pediatric setting.(25) The parental tobacco treatment CDS tool, which interfaces seamlessly within the EHR (EpicCare®, Epic Systems, Inc, Verona, WI, USA), prompts the pediatric clinician to ask the parent about smoking status and assess interest in quitting (at all well-child and acute visits), links to an electronic nicotine replacement therapy prescription for parents interested in quitting, and guides appropriate documentation. Electronic referral to the quitline will be made by clicking an automated link embedded in the tool that will send the parent smokers' names and telephone numbers (entered by the clinician) directly to the Pennsylvania (PA) Free Quitline. This approach matches an existing workflow for CDS for other aspects of pediatric care already successfully in use by the practice.(26)(27)(28)(29) Parent information will be sent using secure, HIPAA-compliant method to transmit protected health information.

Control

All procedures implemented in the standard referral approach will be identical to those in the electronic referral approach with the exception of providing the telephone number for the Quitline to the parent (rather than electronic referral). The clinician workflow will be nearly the same, in that the clinician will use the link embedded in the tobacco treatment CDS tool to add the quitline to the patient's discharge paperwork (rather than automatically refer to the quitline).

Quitline Delivered Treatment

The PA Free quitline is funded by the Pennsylvania Department of Health and staffed by trained cessation counselors available 24 hours a day, 7 days a week, and most holidays. Counseling is available in English and Spanish and can be provided in at least 15 additional languages through a third party. All smokers who enroll in smoking cessation treatment will receive counseling and support consistent with accepted clinical practice guidelines.(32) This treatment includes as many as 5 proactive counseling calls, each designed to help develop problem-solving and coping skills, secure social support, and plan for long-term abstinence. Participants can also call an 800 telephone number as needed for additional support between proactive calls. The timing of counseling calls will be relapse sensitive and include a call 1 or 2 days after the quit date, another telephone call a week after the first call, and additional calls generally occurring at 2- to 3-week intervals thereafter. The call timing will be flexible and adjusted as needed.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

Randomization to the intervention and control approaches will be based on an automatically generated randomization sequence, managed by an honest broker as part of the Department of Biomedical and Health Informatics.

9.2 Data Collection and Management

To minimize the risk of loss of confidentiality, parent subjects will have a unique study number. The generated report that contains parent name and contact information, used to facilitate the clinical referral process, will be stored within PeRC databases managed by DBHi. The Tobacco Quitline will add information about parent smokers who talk with the quitline, are unreachable by the quitline, and enroll or do not enroll in treatment to that report. That report will then be sent back to the DBHi team, who will act as an honest broker and provide this information to the study team in de-identified reports. The study team will have access to the unique study numbers mentioned above but will not be able to link identifiable information with those numbers. Only the Project Director and other senior research staff listed on the protocol will be able to access these de-identified reports. These reports will be password protected and will not be stored on portable media devices (e.g., flash drives).

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. No PHI, managed by DBHi, will be retained for future research, as it will be destroyed after data collection.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

This study presents no more than minimal risk to study participants, as this is a study aimed to improve parent smoker enrollment in the state tobacco quitline. The quitline offers evidence-based tobacco cessation counseling, and referral to this resource is already part of standard practice. The only identifying information that will be collected for parent subjects will be parent participants' name and telephone number. That information, entered during the clinical care encounter by the pediatric clinician, will be collected by an honest broker (within the Department of Biomedical and Health Informatics), and information about parent enrollment in the quitline will be presented back to the study team in de-identified reports. Once data collection is completed, the master list containing the names of the study participants will be deleted by the Department of Biomedical and Health Informatics (DBHi). The Department of Biomedical and Health Informatics will also build the final

analytic data set for the study team. No other PHI identifiers will be collected at any time, and no other PHI identifiers will be stored. The study PI will maintain oversight over data integrity.

9.4.2 Risk Assessment

Risks are not greater than minimal. For parent subjects, because the procedures herein involve accepted forms of treatment interventions and referral to those interventions, we foresee no special risks. The main risk, therefore, to parent subjects is breach of confidentiality. The alternative to participation is parent subject to decide not to be referred to the quitline program.

9.4.3 Potential Benefits of Trial Participation

Although the proposed research poses minimal risks to participants, the benefits to scientific knowledge are numerous. The objectives of the study involve increasing parent smoker enrollment in evidence-based programs that help smokers quit. Helping parent smokers quit not only helps improve their individual health outcomes but also protects their children from the harms of secondhand smoke exposure.

Additionally, the study is novel in two ways. First, it makes use of clinical decision support to guide referral to the smoker quitline by pediatricians for parents who smoke. Second, this study is unique in its attempt to create a systematic bridge between pediatric healthcare setting and adult treatment programs, decreasing logistical barriers to parents receiving services. This study will test if the automated referral improves delivery of care for pediatric patients exposed to SHS and will improve understanding of the technical issues involved in implementing an intervention focused on parents, individuals that are not in the direct care of pediatricians.

9.4.4 Risk-Benefit Assessment

From a risk-benefit assessment perspective, the potential large benefits outweigh the minimal risk posed by the study, justifying proceeding with the trial.

9.5 Recruitment Strategy

Identification of parent smokers will be achieved through the clinical care encounter.

9.6 Informed Consent/Assent and HIPAA Authorization

We request a waiver of obtain informed consent as the research meets the criteria of 45 CFR 46.116(d), in that:

- 1) the research involves no more than minimal risk to the subjects as this is a study aimed to improve parent smoker enrollment in the state tobacco quitline. The quitline offers evidence-based tobacco cessation counseling, and referral to this resource is already part of standard practice.;
-

- 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects as parent smokers are being connected with evidence-based resources that they could already use or not use at their discretion;
- 3) the research could not practicably be carried out without the waiver as obtaining consent would introduce significant bias into the study. Parents referred to the quitline could potentially change their behavior if they knew they were being studied, decreasing the likelihood that they would be willing to be referred (either electronically or the standard approach) to an evidence-based tobacco treatment quitline service. We would not be able to practicably achieve the first objective of the study to determine if electronic referral to the state tobacco quitline for parent smokers increases program enrollment compared to standard referral practice; and,
- 4) after their study participation, the parent subjects will be provided with additional pertinent information about their participation in study aimed at helping parent smokers quit through increased enrollment in the tobacco quitline. This information will be posted throughout the clinic.

9.6.1 Waiver of HIPAA Authorization

We request a waiver of HIPAA authorization as the use of protected health information (parent name and contact information) involves no more than minimal risk to the privacy of the parent subjects based on the presence of the following elements:

- 1) there is an adequate plan to protect the identifiers from improper use and disclosure;
- 2) there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research; and
- 3) the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
 - a. The research could not practicably be conducted without the waiver or alteration (for the reasons detailed above); and
 - b. The research could not practicably be conducted without access to and use of the protected health information (we would not be able to connect parents to the tobacco quitline if their name and contact information was not available).

9.7 Payment to Subjects/Families

No payments will be made to the subjects for participation in the study.

10 PUBLICATION

After completion of the study, a manuscript will be prepared for publication.

11 REFERENCES

1. USDHHS: Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Washington, DC: US Government Printing Office; 2006.
 2. Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, et al. Vital signs: disparities in nonsmokers' exposure to secondhand smoke--United States, 1999-2012. *MMWR Morb Mortal Wkly Rep*. 2015 Feb 6;64(4):103-8.
 3. Wilson KM, Klein JD, Blumkin AK, Gottlieb M, Winickoff JP. Tobacco-smoke exposure in children who live in multiunit housing. *Pediatrics*. 2011 Jan;127(1):85-92.
 4. Johansson A, Hermansson G, Ludvigsson J. How Should Parents Protect Their Children From Environmental Tobacco-Smoke Exposure in the Home? *Pediatrics*. 2004 Apr 1;113(4):e291-5.
 5. Den Exter Blokland EAW, Engels RCME, Hale WW, Meeus W, Willemsen MC. Lifetime parental smoking history and cessation and early adolescent smoking behavior. *Prev Med*. 2004 Mar;38(3):359-68.
 6. Jha P, Ramasundarahettige C, Landsman V, Rostron B, Thun M, Anderson RN, et al. 21st-century hazards of smoking and benefits of cessation in the United States. *N Engl J Med*. 2013 Jan 24;368(4):341-50.
 7. Winickoff JP, Berkowitz AB, Brooks K, Tanski SE, Geller A, Thomson C, et al. State-of-the-Art Interventions for Office-Based Parental Tobacco Control. *Pediatrics*. 2005 Mar 1;115(3):750-60.
 8. Newacheck PW, Stoddard JJ, Hughes DC, Pearl M. Health Insurance and Access to Primary Care for Children. *N Engl J Med*. 1998 Feb 19;338(8):513-9.
 9. Winickoff JP, Tanski SE, McMillen RC, Klein JD, Rigotti NA, Weitzman M. Child health care clinicians' use of medications to help parents quit smoking: a national parent survey. *Pediatrics*. 2005 Apr;115(4):1013-7.
 10. Winickoff JP, Tanski SE, McMillen RC, Hipple BJ, Friebely J, Healey EA. A national survey of the acceptability of quitlines to help parents quit smoking. *Pediatrics*. 2006 Apr;117(4):e695-700.
 11. Oncken CA, Pbert L, Ockene JK, Zapka J, Stoddard A. Nicotine replacement prescription practices of obstetric and pediatric clinicians. *Obstet Gynecol*. 2000 Aug;96(2):261-5.
 12. Zhu S-H, Anderson CM, Tedeschi GJ, Rosbrook B, Johnson CE, Byrd M, et al. Evidence of real-world effectiveness of a telephone quitline for smokers. *N Engl J Med*. 2002 Oct 3;347(14):1087-93.
-

13. Stead LF, Hartmann-Boyce J, Perera R, Lancaster T. Telephone counselling for smoking cessation. *Cochrane Database Syst Rev*. 2013;8:CD002850.
 14. Kruger J, O'Halloran A, Rosenthal AC, Babb SD, Fiore MC. Receipt of evidence-based brief cessation interventions by health professionals and use of cessation assisted treatments among current adult cigarette-only smokers: National Adult Tobacco Survey, 2009-2010. *BMC Public Health*. 2016;16(1):141.
 15. Schauer GL, Malarcher AM, Zhang L, Engstrom MC, Zhu S-H. Prevalence and correlates of quitline awareness and utilization in the United States: an update from the 2009-2010 National Adult Tobacco Survey. *Nicotine Tob Res Off J Soc Res Nicotine Tob*. 2014 May;16(5):544–53.
 16. Zhu S-H, Nguyen QB, Cummins S, Wong S, Wightman V. Non-smokers seeking help for smokers: a preliminary study. *Tob Control*. 2006 Apr;15(2):107–13.
 17. Linder JA, Rigotti NA, Schneider LI, Kelley JHK, Brawarsky P, Haas JS. An electronic health record-based intervention to improve tobacco treatment in primary care: a cluster-randomized controlled trial. *Arch Intern Med*. 2009 Apr 27;169(8):781–7.
 18. Sherman SE, Takahashi N, Kalra P, Gifford E, Finney JW, Canfield J, et al. Care coordination to increase referrals to smoking cessation telephone counseling: a demonstration project. *Am J Manag Care*. 2008 Mar;14(3):141–8.
 19. Boyle R, Solberg L, Fiore M. Use of electronic health records to support smoking cessation. *Cochrane Database Syst Rev*. 2014;12:CD008743.
 20. Vidrine JJ, Shete S, Li Y, Cao Y, Alford MH, Galindo-Talton M, et al. The Ask-Advise-Connect approach for smokers in a safety net healthcare system: a group-randomized trial. *Am J Prev Med*. 2013 Dec;45(6):737–41.
 21. Vidrine JJ, Shete S, Cao Y, Greisinger A, Harmonson P, Sharp B, et al. Ask-Advise-Connect: a new approach to smoking treatment delivery in health care settings. *JAMA Intern Med*. 2013 Mar 25;173(6):458–64.
 22. Jenssen BP, Bryant-Stephens T, Leone FT, Grundmeier RW, Fiks AG. Clinical Decision Support Tool for Parental Tobacco Treatment in Primary Care. *Pediatrics*. 2016;In Press.
 23. Jenssen BP, Shelov ED, Bonafide CP, Bernstein SL, Fiks AG, Bryant-Stephens T. Clinical Decision Support Tool for Parental Tobacco Treatment in Hospitalized Children. *Appl Clin Inform*. 2016;In Press.
 24. Jimenez ME, Fiks AG, Shah LR, Gerdes M, Ni AY, Pati S, et al. Factors associated with early intervention referral and evaluation: a mixed methods analysis. *Acad Pediatr*. 2014 Jun;14(3):315–23.
-

25. Winickoff JP, Nabi-Burza E, Chang Y, Finch S, Regan S, Wasserman R, et al. Implementation of a parental tobacco control intervention in pediatric practice. *Pediatrics*. 2013 Jul;132(1):109–17.
26. Fiks AG, Grundmeier RW, Biggs LM, Localio AR, Alessandrini EA. Impact of Clinical Alerts Within an Electronic Health Record on Routine Childhood Immunization in an Urban Pediatric Population. *Pediatrics*. 2007 Oct 1;120(4):707–14.
27. Fiks AG, Hunter KF, Localio AR, Grundmeier RW, Bryant-Stephens T, Luberti AA, et al. Impact of electronic health record-based alerts on influenza vaccination for children with asthma. *Pediatrics*. 2009 Jul;124(1):159–69.
28. Fiks AG, Grundmeier RW, Mayne S, Song L, Feemster K, Karavite D, et al. Effectiveness of Decision Support for Families, Clinicians, or Both on HPV Vaccine Receipt. *Pediatrics*. 2013 Jun 1;131(6):1114–24.
29. Bell LM, Grundmeier R, Localio R, Zorc J, Fiks AG, Zhang X, et al. Electronic health record-based decision support to improve asthma care: a cluster-randomized trial. *Pediatrics*. 2010 Apr;125(4):e770–7.
30. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999 Sep;89(9):1322–7.
31. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. 2013 Jun;103(6):e38–46.
32. Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline [Internet]. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service; 2008. Available from: http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/treating_tobacco_use08.pdf

APPENDIX

Append relevant information.
